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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,295	VANDEPUTTE, JAN	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-14,16 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-14,16 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on September 25, 2008 is acknowledged. Claims 1, 7-14, 16, and 19-21 remain pending in this application. Claims 20-21 remain withdrawn from consideration. In view of Applicants amendments to the claims, namely, the incorporation of sterilization of the composition, all previous rejections have been withdrawn. However, the following new rejections have been applied.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 7-8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Hymes et al. (US Patent 4,307,717).

Lundmark teaches dispersing honey in polyglycerylmethacrylate, and mixing the honey and the polyglycerylmethacrylate for a sufficient period of time to form a hydrated honey gel polymeric composition" (column 2, lines 54-56). Lundmark discloses, "the products of the present invention may be formulated into lotions, shampoos, hair conditioners, sunscreens, insect repellants and the like" (column 4, lines 60-63). Lundmark additionally discloses a desirable component for use is a glycol. The glycol adds humectant properties to the composition (column 4, lines 18-20). Lundmark discloses, " the preferred polyglycerylmethacrylate is Lubrajel CG, a clathrate formed by

the reaction of glycerin and methylmethacrylate" (column 3, lines 11-24). The presence of glycerin would exhibit the humectant qualities claimed in the instant claim.

Regarding claims 8, Lundmark's Example II discloses 3 formulations of their composition, each comprising between 26.00% and 29.00% honey (column 5, line 18).

Regarding Claims 16, the prior art is silent as to the peroxide number of honey and the LPS content. It is the examiners position that these are properties of the honey and therefore, would necessarily be present in the prior art teachings.

Lundmark does not disclose sterilizing by gamma ray radiation.

Hymes discloses a liquid absorbent, adhesive bandage, in which the combination of the mixture is then subjected to irradiation (usually gamma rays) usually to 2.5 mega rads for sterilization (column 2, lines 65-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the sterilization method taught by Hymes on the composition taught by Lundmark in order to make a composition which is suitable for direct contact with the skin to cover surgical wounds or burn tissue" (Hymes, column 2, lines 23-27).

Applicant would have a reasonable expectation of success in the sterilization of a composition using gamma rays, since irradiation with gamma raise is known in the art as being effective.

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the

percentage of humectants, polymeric gel based on acrylic monomers, honey, polymer, and water, to prepare a composition containing honey for the topical treatment of wounds because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claims 9-10, 12, and 19, rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) and Hymes et al. (US 4,307,717) in view of Stout (US Patent 4,671,267).

Lundmark's and Hymes' teachings are described above and applied in the same manner.

Lundmark and Hymes do not disclose the composition can be used for the healing of wounds, the thickness of the application of the composition, and the gel being a 50% acrylamide, 50% water mixture.

Regarding Claim 9, Stout discloses, "improved therapy members useful for treating of sprains, muscle aches, orthopedic and skin injuries such as burns and other wounds are provided which make use of a pliable, self-sustaining, moisture sorbing gel including a humectants such as glycerin entrapped within a synthetic resin polymer matrix (e.g., a matrix containing acrylic acid or acrylamide monomer moieties)"

(abstract). Stout further discloses, "the gel material can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability" (abstract).

Regarding Claim 12, Stout discloses in Table II and Example 4, a 50% acrylamide in water solution. The examiner is interpreting this to be a mixture that is 50% acrylamide and 50% water.

Regarding Claim 19, Stout discloses, "the preferred gel material provides an excellent dressing for the treatment of burned or otherwise injured skin. In this case a thin (for example from about 0.05 to 0.5 inches) layer of the gel material is hermetically sealed in a sterile package, and in use is simply directly applied to injured skin, without any intermediate cloth covering or the like" (column 3, lines 24-45). 0.05 to 0.5 inches converts to approximately, 1.27mm to 12.7mm, which overlaps the claimed range.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of Lundmark with the teachings of Stout in order to form 'a gel material that can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability. Furthermore, the moisture absorbing and desorbing properties of the gel create a moisture equilibrium between the gel, damaged skin and the atmosphere, thus promoting rapid healing" (abstract).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) and Hymes et al. (US Patent 4,307,717) in view of in view of Stout (US Patent 4,671,267) and further in view of Dell (US Patent 4,542,012).

Lundmark's and Hymes' teachings as they apply to Claim 1 are described above.

Lundmark and Hymes do not disclose the use of acrylamide or analog compounds consisting of diacetone acrylamide, vinyllactam, N-alkylated acrylamide, N,N-diakylated acrylamide, N-vinylpyrrolidone, or acryloylmorpholin.

Stout teaches the use of acrylamide as a monomer, however, Stout does not teach the use of analog compounds.

Dell discloses, "a dermatologically acceptable, film-forming composition which comprises a film-forming polymer and, as a broad spectrum antimicrobial agent. The composition when applied to the skin from a fugitive solvent form a substantially water-insoluble, tack-free, flexible film, which adheres to the skin, releases the antimicrobial agent. (abstract).

Dell disclosed the polymer being "a polyvinylpyrrolidone polymer which is the free-radical-polymerization reaction product of at least N-vinylpyrrolidone and a vinyl-functional compound" (column 2, lines 43-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have expanded upon the teachings of Lundmark and Stout, with the polymer taught by Dell, in order to form "a good film-forming composition should be dermatologically-acceptable and capable of application to skin conveniently as a solution in a dermatologically-acceptable, volatile solvent. The film resulting from application of such a solution should be bacteria-impermeable, water-insoluble, and nontacky and should permit facile transmission of water vapor there through. It should adhere suitably to skin and be capable of releasing the antimicrobial agent onto the skin

over a period of time to promote asepsis for a suitably long period of time" (column 2, lines 3-24).

The Applicant would have a reason expectation of success since N-vinylpyrrolidone is commonly used as a film-forming polymer in cosmetic formulations. It would be within the knowledge of one of ordinary skill in the art to substitute it for an acrylic polymer used for the same function.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) and Hymes et al (US Patent 4,307,717) in view of Trenzeluk (US Patent 4,857,328).

Lundmark's and Hymes' teachings are described above and applied in the same manner.

Lundmark and Hymes do not disclose the use of antioxidants, transretinoic acid and/or derivatives and precursors thereof, polyunsaturated fatty acids, n-hexacosanol, bis(maltolato)oxo-vanadium(IV), aloe vera, and thickeners. Lundmark also does not disclose a percentage of additives.

Trenzeluk discloses" a skin therapeutic mixture is useful for the alleviation of certain skin disorders such as acne, psoriasis, burns, pimples, blackheads, and open sores: the therapeutic agent being the extract from the dried leaves of the aloe vera plant; the skin therapeutic mixture comprises about 7.4% by weight of the extract from the dried leaves of the aloe vera plant as the therapeutic agent" (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have added aloe vera to a skin care composition, since aloe is well known in the art for its soothing effects, fragrance, and healing qualities.

The applicant would have a reason expectation of success since the use of aloe vera is well known in the art for the same reasons and qualities applicant is claiming.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues Lundmark discloses a honey preparation for cosmetic treatment of keratinous substrates, wherein the honey is a preferred source of liquid polysaccharide. Furthermore, Lundmark discloses other possible sources of liquid polysaccharide such as high fructose corn syrup. Applicant thus argues Lundmark teaches away from the claimed invention. The examiner respectfully disagrees with Applicants conclusion that Lundmark teaches away from the claimed invention. While Lundmark may disclose additional liquid polysaccharides, the use of honey is disclosed, and therefore reads on the instant claims. Applicant is directed to MPEP 2123, which discloses patents are relevant as prior art for all they contain including non preferred embodiments.

Applicant further argues Lundmark does not disclose the antibacterial property of the honey. It is respectfully submitted that Lundmark need not recognize such a functional inherent property.

Applicant further argues Lundmark does not disclose his composition to be used as a treatment for wounds. It is again noted and Applicant is reminded that Applicant is claiming a composition and not a method of treatment in the rejected claims; therefore, the future intended use or function of the composition does not hold patentable weight.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While it is acknowledged that each single reference does not disclose Applicants complete invention, the rejection is based on a combination of the two references. Hymes discloses the advantages of using gamma ray radiation for the sterilization of a topical formulation. Therefore, it is the position of the examiner that it would have been obvious to apply such a treatment to other formulations including Lundmark to illicit the same advantage.

Applicant did not provide any arguments regarding the teachings of Stout, Dell, and Trenzeluk therefore; the examiner is of the opinion that Applicant has accepted those teachings for their relevance to the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615